

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Application For: United States Patent No. 5,688,657

Title: MONOCLONAL ANTIBODIES AGAINST
CARCINOMA-ASSOCIATED ANTIGENS
AND USES THEREFOR

Patent Appln. Filed: September 12, 1994

Patent Issued: November 18, 1997

Assignee: International Bio-Immune Systems, Inc.

Patent Group Art Unit: 1652

Reissue Applicants: Kwong Y. Tsang and Myron Arlen

Reissue Serial No.: to be assigned

Reissue Appln. Filed: herewith

REISSUE APPLICATION, DECLARATION AND POWER OF ATTORNEY

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Assistant Commissioner for Patents
Washington, D.C. 20231
Box Reissue

SIR:

WE, Kwong Y. Tsang and Myron Arlen, the below named inventors, hereby declare as follows:

Our residences, post office addresses and citizenship are as stated below next to our names.

We believe that we are the original, first and joint inventors of the invention described and claimed in United States Letters Patent No. 5,688,657 ("the '657 patent"), entitled "MONOCLONAL ANTIBODIES AGAINST CARCINOMA-ASSOCIATED ANTIGENS AND USES THEREFOR", which issued on November 18, 1997, and of the above-identified reissue application, which is appended hereto and by which we solicit a reissue patent.

I. REVIEW OF PAPERS AND DUTY OF CANDOR

We have reviewed and understand the contents of the above-identified patent, including the issued claims, and the reissue application appended hereto, including the claims thereof.

We acknowledge the duty to disclose information which is material to the examination of this reissue application, in accordance with 37 C.F.R. §1.56.

II. PRIORITY CLAIM

The above-identified reissue application is based on the '657 patent which is a continuation-in-part of Ser. No. 159,836, filed November 30, 1993, abandoned, which is a continuation-in-part of Ser. No. 117,430, September 7, 1993, abandoned, which is a continuation-in-part of Ser. No. 670,816, March 18, 1991, abandoned, which is a continuation-in-part of Ser. No. 176,337, March 31, 1988, abandoned.

III. OFFER TO SURRENDER ORIGINAL LETTERS PATENT

We and our assignee hereby offer to surrender the original letters patent, or provide an appropriate affidavit or declaration in the event that the original patent is lost, upon an indication of allowability of this reissue patent application.

IV. STATEMENT OF INOPERATIVENESS OF THE ISSUED PATENT

We believe the original patent to be potentially inoperative because of an error that arose without any deceptive intention on our parts as applicants therefor, which resulted in an erroneous deposit of the hybridoma cell lines referred to in the patent as ATCC accession numbers HB-12314 and HB-12315.

V. SPECIFICATION OF "ERRORS" RELIED UPON AND HOW THEY AROSE

The following is a description of the manner in which the errors specified below are believed to have occurred in the deposit of the hybridoma cell lines HB-12314 and HB-12315 referred to in the '657 patent. Although the following account does not describe our own actions, on information and belief we believe it to be true.

On March 13, 1997, to enable claims directed towards mAb 31.1 and 33.28, International Bio-Immune Systems, Inc ("IBS"), assignee of the above identified application, deposited with the American Type Culture Collection ("ATCC") what was believed to be the murine hybridoma cell lines that produce the monoclonal antibodies mAb 31.1 and mAb 33.28. The deposited cell lines were assigned accession numbers HB-12314 and HB-12315, respectively.

In September 1998, Purdue Pharma, a licensee of the '657 patent, requested a sample of the murine 31.1 antibody. IBS thereafter supplied Purdue a sample of antibody, now believed to be produced by the same hybridoma cell line deposited with the ATCC and assigned accession number HB-12314. In October and November of 1998, Purdue Pharma presented data indicating that presumed 31.1 antibody did not have the expected biological properties, *i.e.*, it did not compete with an antibody known to bind to the same antigen recognized by the 31.1 antibody.

Concerned about the identity of the murine hybridoma cell line, IBS obtained the DNA sequence encoding a portion of the variable heavy region of the monoclonal antibody secreted by the cell line and determined that the cell line was not producing the expected 31.1 antibody. With regard to the 33.28 antibody, when immunohistochemical studies were performed, the secreted antibody was found not to have the expected immunospecificity.

It is now believed that an employee of IBS had mistakenly mislabeled tubes believed to contain both the murine hybridoma cell lines producing the 31.1 and 33.28 monoclonal antibodies when preparing frozen samples of the cells for storage purposes. The samples of hybridoma cells deposited with the ATCC are believed to have been prepared from cultures derived from mislabeled frozen cells, thus resulting in erroneous deposits of the HB-12314 and HB-12315 hybridoma cell lines referred to in the patent. Accordingly, the mAbs

made available via the ATCC depository are believed not to be the mAbs claimed, and hence the specification of the '657 patent is defective.

VI. POWER OF ATTORNEY

Applicants and the assignee hereby appoint the following attorneys of the firm of Baker & Botts, L.L.P., having an address at 30 Rockefeller Plaza, New York, NY 10112 as their attorneys, with full power of substitution and revocation, to prosecute this reissue application and to transact all business in the Patent and Trademark Office connected therewith: Dana M. Raymond, Reg. No. 18,540; Frederick C. Carver, Reg. No. 17,021; Francis J. Hone, Reg. No. 18,662; Joseph D. Garon, Reg. No. 20,420; Arthur S. Tenser, Reg. No. 18,839; Ronald B. Hildreth, Reg. No. 19,498; Thomas R. Nesbitt, Jr., Reg. No. 22,075; Robert Neuner, Reg. No. 24,316; Richard G. Berkley, Reg. No. 25,465; Richard S. Clark, Reg. No. 26,154; Bradley B. Geist, Reg. No. 27,551; James J. Maune, Reg. No. 26,946; John D. Murnane, Reg. No. 29,836; Henry Tang, Reg. No. 29,705; Robert C. Scheinfeld, Reg. No. 31,300; John A. Fogarty, Jr., Reg. No. 22,348; Louis S. Sorell, Reg. No. 32,439; Rochelle K. Seide Reg. No. 32,300; Gary M. Butter, Reg. No. 33,841; Marta E. Delsignore, Reg. No. 32,689; and Lisa B. Kole, Reg. No. 35,225.


Please address all communications regarding this application to:

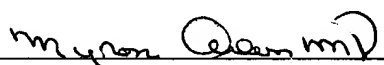
Lisa B. Kole, Esq.
Baker & Botts, L.L.P.
30 Rockefeller Plaza
New York, NY 10112

VII. DECLARATION

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United

States Code, and that such willful and false statements may jeopardize the validity of the application or any patent issued thereon.

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ASSENT BY ASSIGNEE

International Bio-Immune Systems, Inc., the assignee of the entire right, title and interest in United States Patent No. 5,688,657, entitled "MONOCLONAL ANTIBODIES AGAINST CARCINOMA-ASSOCIATED ANTIGENS AND USES THEREFOR" pursuant to the assignment recorded in the records of the United States Patent Office at reel 6895, frame 803, hereby assents to the filing of the reissue application for said Patent No. 5,688,657 that is attached to this Declaration, and confirms reissue applicants' offer to surrender the original '657 patent as stated therein, and to the appointment of power of attorney as stated therein.

International Bio-Immune Systems, Inc.

Date: May 8, 2000

By : 
Signature

Name : Andrew Lin

Title : Chief Operating Officer

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Application for: U.S. Patent No. 5,688,657

Applicants : Tsang, K.Y. and Arien, M.

Title: MONOCLONAL ANTIBODIES AGAINST HUMAN COLON
CARCINOMA-ASSOCIATED ANTIGENS AND USES THEREFOR

Patent Application Filed: September 12, 1994

Patent Issued: November 18, 1997

Patent Serial No.: 304,524

Assignees: International Bio-Immune Systems, Inc.

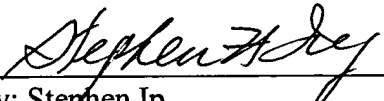
Reissue Serial No.: To Be Assigned

POWER OF ATTORNEY

Applicant hereby appoints Dana M. Raymond, Reg. No. 18,540; Frank W. Ford, Jr., Reg. No. 16,614; Frederick C. Carver, Reg. No. 17,021; Francis J. Hone, Reg. No. 18,662; Joseph D. Garon, Reg. No. 20,420; Arthur S. Tenser, Reg. No. 18,839; Ronald B. Hildreth, Reg. No. 19,498; Thomas R. Nesbitt, Jr., Reg. No. 22,075; Robert Neuner, Reg. No. 24,316; Richard G. Berkley, Reg. No. 25,465; Richard S. Clark, Reg. No. 26,154; Thomas D. MacBlain, Reg. No. 24,583; Bradley B. Geist, Reg. No. 27,551; James J. Maune, Reg. No. 26,496; John D. Murnane, Reg. No. 29,836; Henry Tang, Reg. No. 29,705; Robert C. Scheinfeld, Reg. No. 31,300; John A. Fogarty, Jr., Reg. No. 22,348; Louis S. Sorell, Reg. No. 32,439; Rochelle K. Seide, Reg. No. 32,300; Gary M. Butter, Reg. No. 33,841; Marta E. Delsignore, Reg. No. 32,689, and Lisa B. Kole, Reg. No. 35,225; of the firm of BAKER & BOTTS, L.L.P., 30 Rockefeller Plaza, New York, New York, 10112-0228, as attorneys to prosecute the above-identified international application and to transact all business connected therewith.

Please address all future correspondence to BAKER & BOTTS, L.L.P., 30
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Dated:


By: Stephen Ip
Chief Executive Officer

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